

SEP 23 2009

**510(k) Summary of Safety and Effectiveness:  
VariAx Elbow System Line Extension****Submission Information**Name and Address of the Sponsor  
of the 510(k) Submission:Howmedica Osteonics Corp.  
325 Corporate Drive  
Mahwah, NJ 07430

For Information contact:

Melissa A. Matarese, Regulatory Affairs Associate  
Howmedica Osteonics Corp.  
325 Corporate Drive  
Mahwah, NJ 07430  
Phone: (201) 831-5116  
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Date Summary Prepared:

August 28, 2009

**Device Identification**

Proprietary Name:

VariAx Elbow System Line Extension

Common Name:

Bone plates and screws

Classification Name and Reference:

Single/multiple component metallic bone fixation  
appliances and accessories, 21 CFR §888.3030

Device Product Code:

HRS: Plate, Fixation, Bone

**Description:**

The subject VariAx Elbow System is comprised of plates and screws, manufactured from Titanium alloy and Commercially Pure Titanium. The subject system was determined substantially equivalent in K073527. This Special 510(k) submission is intended to address the addition of the 7mm washer to the predicate VariAx Elbow System.

**Intended Use:**

The VariAx Elbow System Line Extension does not alter the intended use of the predicate systems as cleared in their respective premarket notifications. The indications for use for the subject plates are provided below.

**Indications for Use:**

The VariAx Elbow System Line Extension is intended for fracture fixation of long bones. Indications include distal humerus and proximal ulna.

**Statement of Technological Comparison:**

The features of the subject components are substantially equivalent to the predicate devices based on similarities in intended use and design. Mechanical testing demonstrates substantial equivalence of

the subject components to the predicate device in regards to mechanical strength. In addition, the intended use, manufacturing methods, packaging, and sterilization of the predicate and subject components are identical.

The subject and predicate devices are made from Titanium (Ti-6Al-4V). Functional and mechanical testing demonstrates the comparable mechanical & functional properties of the subject VariAx Elbow System Line Extension to the predicate device VariAx Elbow System K073527. The washer has been cleared for use in K000080 and K000636.



DEPARTMENT OF HEALTH & HUMAN SERVICES

SEP 23 2009

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Mail Center - WO66-G609  
Silver Spring, MD 20993-0002

Howmedica Osteonics Corp.  
% Ms. Melissa A. Matarese  
Regulatory Affairs Associate  
325 Corporate Drive  
Mahwah, New Jersey 07430

Re: K092671

Trade/Device Name: VariAx Elbow System Line Extension  
Regulation Number: 21 CFR 888.3030  
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories  
Regulatory Class: II  
Product Code: HRS  
Dated: August 28, 2009  
Received: August 31, 2009

Dear Ms. Matarese:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", with a stylized flourish at the end.

Mark N. Melkerson  
Director  
Division of Surgical, Orthopedic,  
and Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K 092671

Device Name: VariAx Elbow System Line Extension

## Indications For Use:

The VariAx Elbow System Line Extension is intended for fracture fixation of long bones.  
Indications include distal humerus and proximal ulna.

Prescription Use   X  

(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use           

(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF  
NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

*Jonathan J. for MCM*  
(Division Sign-Off)  
Division of Surgical, Orthopedic,  
and Restorative Devices

510(k) Number K092671